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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,911	03/16/2004	Harada Yosuke	Q-80506	9558
23373	7590	11/13/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,911

Applicant(s)

YOSUKE ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A (sequence alignment)</u> . |

DETAILED ACTION

Claim 10 is pending and examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "under stringent conditions" but it is not clear what the metes and bounds are. The specification does not define the limitation, and one in the art would have difficulty determining which nucleic acid molecules are within the property boundary of the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicable standard for the written description requirement can be found: MPEP 2163; *University of California v. Eli Lilly*, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; *Enzo Biochem Inc. v. Gen-Prove Inc.*, 63 USPQ2d 1609; *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111; and *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in a form of hybridizing molecule. There is not even identification of function associated with the hybridizing molecules. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the

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encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO: 2. Therefore, only isolated nucleic acid comprising SEQ ID NO:2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 10 is rejected under 35 U.S.C. 102(e) as being anticipated by US PAT, 5,932,445 (hereinafter the '445 patent filing date Nov. 7, 1997).

Claim 10 is drawn to polynucleotide capable of hybridizing to SEQ IDS NO: 2 under stringent conditions.

The '445 patent discloses a polynucleotide that matches 100% from nucleotide #96 to about 1056 of the instant SEQ ID NO: 2, which is about 1000 nucleotides long. See attached Exhibit A (4 pages total) This nucleotide would be capable of hybridizing to the instant SEQ ID NO:2.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 10 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,822,083.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 are species of the genus claim 10 of the instant application, thus claims 1-3 of the patent anticipates the instant claim 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

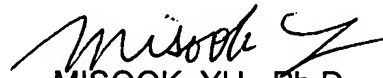

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642

Exhibit A

Title: US-10-800-911-2
 Perfect score: 2382
 Sequence: 1 atgcgggtccggatagggtct.....cagagcagcagccaccacag 2382

Scoring table: IDENTITY_NUC
 Gapop 10.0 , Gapext 1.0

Searched: 1403666 seqs, 935554401 residues

Total number of hits satisfying chosen parameters: 2807332

Minimum DB seq length: 0

Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
 Maximum Match 100%
 Listing first 45 summaries

Database : Issued_Patents_NA:*

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- 2: /EMC_Celerra_SIDS3/ptodata/2/ina/5_COMB.seq:*
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- 9: /EMC_Celerra_SIDS3/ptodata/2/ina/RE_COMB.seq:*
- 10: /EMC_Celerra_SIDS3/ptodata/2/ina/backfiles1.seq:*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	% Match	Query Length	ID	Description
1	2382	100.0	2382	3 US-09-555-367A-2	Sequence 2, Appli
2	2378.8	99.9	7885	3 US-09-555-367A-3	Sequence 3, Appli
3	972.6	40.8	1124	2 US-08-966-316-11	Sequence 11, Appl
4	892	37.4	1701	3 US-09-991-181-114	Sequence 114, App
5	892	37.4	1701	3 US-09-990-444-114	Sequence 114, App

A

RESULT 3
 US-08-966-316-11
 ; Sequence 11, Application US/08966316
 ; Patent No. 5932445
 ; GENERAL INFORMATION:
 ; APPLICANT: Lal, Preeti
 ; APPLICANT: Au-Young, Janice
 ; APPLICANT: Reddy, Roopa
 ; APPLICANT: Murry, Lynn E.
 ; APPLICANT: Mathur, Preete
 ; TITLE OF INVENTION: SIGNAL PEPTIDE - CONTAINING PROTEINS
 ; NUMBER OF SEQUENCES: 18
 ; CORRESPONDENCE ADDRESS:
 ; ADDRESSEE: Incyte Pharmaceuticals, Inc.
 ; STREET: 3174 Porter Drive
 ; CITY: Palo Alto
 ; STATE: CA
 ; COUNTRY: USA
 ; ZIP: 94304
 ; COMPUTER READABLE FORM:
 ; MEDIUM TYPE: Diskette
 ; COMPUTER: IBM Compatible
 ; OPERATING SYSTEM: DOS
 ; SOFTWARE: FastSEQ for Windows Version 2.0
 ; CURRENT APPLICATION DATA:
 ; APPLICATION NUMBER: US/08/966,316
 ; FILING DATE: Herewith
 ; CLASSIFICATION: 435
 ; PRIOR APPLICATION DATA:
 ; APPLICATION NUMBER:
 ; FILING DATE:
 ; ATTORNEY/AGENT INFORMATION:
 ; NAME: Billings, Lucy J.
 ; REGISTRATION NUMBER: 36,749
 ; REFERENCE/DOCKET NUMBER: PF-0424 US
 ; TELECOMMUNICATION INFORMATION:
 ; TELEPHONE: 650-855-0555
 ; TELEFAX: 650-845-4166
 ; TELEX:
 ; INFORMATION FOR SEQ ID NO: 11:
 ; SEQUENCE CHARACTERISTICS:
 ; LENGTH: 1124 base pairs
 ; TYPE: nucleic acid
 ; STRANDEDNESS: single
 ; TOPOLOGY: linear
 ; IMMEDIATE SOURCE:
 ; LIBRARY: LEUKNOT03
 ; CLONE: 1880692
 US-08-966-316-11

Query Match 40.8%; Score 972.6; DB 2; Length 1124;
 Best Local Similarity 98.6%; Pred. No. 3.5e-284;
 Matches 981; Conservative 0; Mismatches 14; Indels 0; Gaps 0;

Qy	1	ATGCGGGTCCGGATAGGGCTGACGCTGCTGCTGTGTGCGGTGCTGCTGAGCTTGGCCTCG	60
Db	96	ATGCGGGTCCGGATAGGGCTGACGCTGCTGCTGTGTGCGGTGCTGCTGAGCTTGGCCTCG	155
Qy	61	GCGTCCTCGGATGAAGAAGGCAGCCAGGATGAATCCTTAGATTCCAAGACTACTTTGACA	120
Db	156	GCGTCCTCGGATGAAGAAGGCAGCCAGGATGAATCCTTAGATTCCAAGACTACTTTGACA	215

Qy	121	TCAGATGAGTCAGTAAAGGACCATACTACTGCAGGCAGAGTAGTTGCTGGTCAAATATTT	180
Db	216	TCAGATGAGTCAGTAAAGGACCATACTACTGCAGGCAGAGTAGTTGCTGGTCAAATATTT	275
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Db	276	CTTGATTCAGAAGAATCTGAATTAGAATCCTCTATTCAAGAAGAGGAAGACAGCCTCAAG	335
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Qy	301	AACAAGGACTATGAAGAGCCAAAGAAAGTACGGAAACCAGCTTTGACCGCCATTGAAGGC	360
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Qy	361	ACAGCACATGGGGAGCCCTGCCACTTCCCTTTTCTTTTCTAGATAAGGAGTATGATGAA	420
Db	456	ACAGCACATGGGGAGCCCTGCCACTTCCCTTTTCTTTTCTAGATAAGGAGTATGATGAA	515
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Db	516	TGTACATCAGATGGGAGGGAAGATGGCAGACTGTGGTGTGCTACAACCTATGACTACAAA	575
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Qy	661	GCCCTGGAGAGAGTGTATATGCTCTTTTATTTGGTGATTACTTGCCACAGAATATCCAG	720
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Qy	721	GCAGCGAGAGAGATGTTTGAGAAGCTGACTGAGGAAGGCTCTCCAAGGGACAGACTGCT	780
Db	816	GCAGCGAGAGAGATGTTTGAGAAGCTGACTGAGGAAGGCTCTCCAAGGGACAGACTGCT	875
Qy	781	CTTGGCTTTCTGTATGCCTCTGGACTTGGTGTTAATTCAAGTCAGGCAAAGGCTCTTGTA	840
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